



**MEDI-CAL DRUG USE REVIEW BOARD
MEETING MINUTES
Tuesday, September 10, 2013
10:30 a.m. – 1 p.m.**

Location: Department of Health Care Services
1500 Capitol Avenue
Training Rooms B+C
Sacramento, CA 95814

Topic	Discussion
1) WELCOME/ INTRODUCTION	<ul style="list-style-type: none"> • The meeting was called to order by the Chair of the Board, Dr. Marilyn Stebbins • Board members present: Drs. Marilyn Stebbins, Timothy Albertson, Patrick Finley, Janeen McBride, Robert Mowers and Andrew Wong • Board members absent: Dr. Stephen Stahl • Board members and attendees introduced themselves. • Mike Wofford, Pharm.D. Chief of Pharmacy Policy Branch of Pharmacy Benefits Division (PBD), Pauline Chan, R.Ph. and other pharmacist staff from the division, including Folashade Naku, R.Ph. were present and introduced.
2) CALL TO ORDER/ REVIEW AND APPROVAL OF MAY 14, 2013 MINUTES	<ul style="list-style-type: none"> • Patrick Robinson, R.Ph. (Xerox) announced that the DUR Board meetings are now being recorded with a handheld audio-recording device, starting with today's meeting. • Patrick Robinson reminded everyone to sign in and described two Listservs available to the public. One list serve is the Medi-Cal Subscription Service (MCSS). There is a table outside the meeting room to sign up. Patrick also keeps a second Listserv to tell people about the DUR quarterly meetings. To sign up for the second Listserv, attendees may leave their business cards with Patrick after the meeting. • Pauline Chan announced Jannice Tan was leaving the group. Jannice Tan was thanked for her service to the DUR program. • Pauline Chan was interested in knowing how many people had subscribed to MCSS. • The Medi-Cal Drug Use Review Board (the "Board") reviewed the May 14, 2013, minutes. Upon review of the minutes, Dr. Stebbins indicated she was not at the meeting, but indicated she disagreed with what was noted in the minutes regarding the MIS/DSS update section. Her recollection of the call with Director Toby Douglas was that the Board was not told that the MIS/DSS request was denied at their meeting with Director Douglas and discussions were still ongoing regarding Board access to the MIS/DSS database. Dr. Stebbins indicated Director Douglas had encouraged the Board to meet again to continue the dialogue. Dr. Wong added that he chaired the May 14 meeting and the minutes reflected what Dr. Wofford had said at the meeting. Dr. Wofford clarified that the denial was a response to the Xerox letter requesting MIS/DSS access, and that this denial had occurred prior to the meeting with the Board. Dr. Stebbins stated the Board intends to meet with Director Douglas and Dr. Wofford at a later date to reopen the MIS/DSS access issue. • Dr. Finley asked if there was information from other states with both fee-for-service programs and managed care regarding how their DUR Board handles their data and cost. Dr. Stebbins stated that this information may not need to be presented at the board meeting, but there should be information from other states, as every state must have to deal with the same issue and asked

	<p>Pauline Chan to collect this information.</p> <ul style="list-style-type: none"> • Dr. Stebbins made a two-part motion to: 1) look at how other state DUR Boards look at their data when they have both a managed and a FFS side and 2) to reopen the discussion with Director Douglas and Dr. Wofford to see how other state DUR Boards handle the issue of cost. The motion was seconded and approved. <p>ACTION ITEM: Look at how other state DUR Boards evaluate their data when they have both a managed and a FFS side and 2) reopen the discussion with Director Douglas and Dr. Wofford to see how other state DUR Boards handle the issue of cost.</p> <ul style="list-style-type: none"> • Dr. Wong stated he had two grammatical edits to the minutes and he would provide these to Patrick Robinson. • Dr. Stebbins made a motion to amend the minutes to reflect the MIS/DSS denial was prior to, but not at the meeting with Director Douglas. The motion was seconded and was approved. <p>ACTION ITEM: Edit the minutes to reflect Dr. Stebbins' understanding of the time of denial of MIS/DSS access, and incorporate Dr. Wong's edits into the minutes.</p>
3) OLD BUSINESS	<p>a. Review of Action Items From Previous Board Meeting:</p> <p>i. CMS Annual Report: Pauline Chan noted that the FFY 2012 CMS Annual Report cover letter was signed by the DUR Board Chair, Dr. Stebbins. The report was submitted to the Centers for Medicare and Medicaid Services (CMS) on June 28, 2013.</p> <p>Pauline Chan also informed the Board of the updated CMS website for Drug Utilization Review: http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Drug-Utilization-Review.html. This site contains the Medicaid Drug Utilization Review Annual Report Survey template, which each state is required to use to prepare the annual report. This site also provides the DUR program description and guidelines. Additionally, annual reports for all fifty states are available at this site, including previous years of 2010 and 2011.</p> <p>Patrick Robinson mentioned that the link for the "Drug Utilization Review Annual Report" section on the Medi-Cal DUR home page main menu (http://files.medi-cal.ca.gov/pubsdoco/dur/dur_home.asp) is linked to the updated CMS website.</p> <p>For the 2011 DUR Annual Report, CMS highlighted innovative practices of states across the country. Pauline Chan informed the Board that California was mentioned twice for innovative practices: 1) for antipsychotic drug monitoring; and 2) for disseminating educational information to providers in a timely fashion. Pauline Chan commended the Board and the DUR program staff for their hard work.</p> <p>ii. Comprehensive Diabetes Care educational bulletin: As a follow-up to the educational bulletin, Amanda Fingado, MPH (UCSF) presented the HbA1C and LDL screening data stratified by geographic region, concomitant antipsychotic use, and other demographic characteristics (gender, age, ethnicity/race). Screening rates were lowest in the Bay Area region, where during the measurement year only 12.4% of the study population had at least one HbA1C screening and only 9.5% had at least one LDL screening. Dr. Stebbins suggested that there was insufficient data to analyze, since the managed care medical claims data are not available. Dr. Albertson noted that there is great opportunity for improvement using available data, as these screening numbers are so low it warrants further action. Dr. Stebbins stated that some pharmacies are now performing fingersticks and cholesterol screenings in community pharmacies. Dr. Albertson noted these are good examples of team approach; and that a multi-disciplinary approach is needed, since the physician could only remind or encourage the patient to follow up, but cannot make them to do so. Dr. Wong shared that he has been impressed with initiatives where pharmacists provide education to patients, including discharge medication(s) education. Dr. Stebbins noted that education alone is insufficient, but wanted to go on record to state she thinks there are ways to tackle this problem that aren't being done</p>

	<p>right now that might go a long way in improving the care of these patients. Pauline Chan suggested reviewing the claims data for high-volume prescribers and pharmacies with high-volume dispensing.</p>
4) NEW BUSINESS	<p>a. Board Activities: Dr. Stebbins noted in Dr. Finley's absence that he is working on submission of his article entitled, "Detection and Treatment of Perinatal Depression in a State Medicaid Population." In addition, he is working with DHCS to get access to data for another project. Dr. Albertson noted that he is interested in examining medication use in asthmatics. He is hoping to be able to identify how many Medi-Cal beneficiaries carry the diagnosis of asthma and what proportion of these individuals are on short- and/or long-acting short-acting beta-2-receptor agonist.</p> <p>b. Pharmacy Update: Pauline Chan stated that sections of the DUR manual will be reviewed on a rotating schedule, in order to complete a full review of the entire manual every 2 years. The section presented today is Section 10, DUR: Introduction, which describes the Board's responsibilities in the compilation of the Medicaid DUR Annual Report, which is submitted to CMS. Section 10 in the Medi-Cal DUR manual is outdated and is inconsistent with CMS requirements. Proposed revisions include adding information about the Medicaid Drug Utilization Review Annual Report Survey. Dr. Stebbins noted that because the Board is mostly focused on the Medi-Cal fee-for-service population and not as much on the Medi-Cal Managed Care population, DHCS might want to clarify this in the Medi-Cal DUR manual at some point in future edits.</p> <p>ACTION ITEM: Revise Section 10, DUR: Introduction in the Medi-Cal DUR manual with updated annual report information and present to the Board at the next meeting.</p> <p>c. Quarterly Report – 1Q2013 (January – March 2013): Amanda Fingado presented the DUR quarterly report for the 1st quarter of 2013. She noted that utilization of barbiturates and benzodiazepines decreased for Medi-Cal full-benefit beneficiaries who are dually-eligible for Medicare Part D starting on January 1, 2013, when barbiturates "used in the treatment of epilepsy, cancer, or a chronic mental health disorder" and benzodiazepines were covered through Medicare Part D. Lorazepam and clonazepam both dropped out of the top 20 drugs by percentage of utilizing beneficiaries with a paid claim, in comparison to the prior quarter when these drugs were covered through Medi-Cal.</p> <p>d. Quarterly Report – 2Q2013 (April – June 2013): Amanda Fingado presented the DUR quarterly report for the 2nd quarter of 2013. She noted that a policy change from First DataBank was responsible for a significant drop in the total prospective DUR alerts for low-dose (LD) levothyroxine, which had been the top ranked-drug in total number of LD alerts before the policy change. The minimum dosage was lowered for all beneficiaries less than 18 years of age and resulted in a corresponding decrease in LD alerts for levothyroxine from the prior quarter. In addition, among the 18 year-and-under age groups, the spike in total utilizing beneficiaries in 2013 Q1 seems to have normalized during 2013 Q2. During 2013 Q1, increases were shown in total utilizing beneficiaries from both the 0-12 year age group (increase of 18%) and the 13-18 year age group (increase of 8%), while in 2013 Q2, total utilizing beneficiaries dropped 17% in the 0-12 year age group and 6% in the 13-18 year age group. However, within these two age groups the total number of utilizing beneficiaries still remains slightly higher than the prior year.</p> <p>e. Prospective DUR presented by Amanda Fingado</p> <p>i. Review of DUR Alert: Maximum Duration (MX)</p> <ul style="list-style-type: none"> • While the DUR alert for excessive duration (MX) is turned on for the drugs appearing on the Target Drug List for this alert, it is not working properly at this time and is inactive. However, Sections 20 and 35 of the Medi-Cal DUR manual do not indicate this alert is inactive. • The Board agreed that the DUR manual should be updated to be an accurate reflection of the current DUR system. <p>ii. Review of Prospective DUR Criteria: Antipsychotics</p> <ul style="list-style-type: none"> • A review of the antipsychotic drug class showed inconsistencies between drugs that appear

	<p>on the main DUR target drug list and drugs that have alerts turned on for prospective DUR. In addition, within drug therapeutic categories there are also inconsistencies between drugs, alert status, and whether or not drugs are on the main DUR target drug list. The Board reviewed all antipsychotic drug therapeutic categories for: 1) appropriateness of prospective DUR alerts and 2) consistency of prospective DUR alerts.</p> <p>ACTION ITEM: A summary of the Board recommendations for updating the DUR target drug list and formulary file alert table for antipsychotics will be submitted to DHCS for review.</p> <p>iii. Review of Prospective DUR Criteria: Added Generic Code Number (GCN) sequence numbers</p> <ul style="list-style-type: none"> Each week new Generic Code Number (GCN) sequence numbers are added and the current system is to turn on prospective DUR alerts only for overutilization (ER) and level 1 severity drug-drug interactions (DD). However, due to a lack of a systematic review process for incoming GCNs, discrepancies have been identified within drug therapeutic categories and among different formulations of the same drug, where alerts for new formulations of drugs (new GCNs) are not consistent with alerts for previous formulations (existing GCNs). A process was suggested to the Board for a weekly review of the new GCNs added each week where: 1) the Xerox DUR pharmacist (Patrick Robinson) will review the list each week and review the drug description for drugs currently on the Medi-Cal target drug list for prospective DUR alerts, 2) if a GCN for a drug on the Medi-Cal target drug list for prospective DUR alerts is identified, the prospective DUR alert profile for the existing GCNs will be used to set the prospective DUR alert profile for the new GCN, 3) GCNs will be reviewed before any prospective DUR alert is turned on to make sure they are not for bulk formulations, and 4) a list of GCNs with prospective DUR alerts turned on will be provided to both DHCS and the Board each quarter for review. Recommendations for further investigation or to turn off alerts will be taken at that time. The Board agreed that new GCNs should be reviewed for prospective DUR alerts, in order to ensure consistency with alerts for previous formulations (existing GCNs).
	<p>f. Review of DUR Publications presented by Dr. Shal Lynch (UCSF):</p> <p>i. DUR Educational Alert (July, 2013): Codeine Use in Children after Tonsillectomy and/or Adenoidectomy</p> <ul style="list-style-type: none"> This alert summarized a recent FDA Drug Safety Communication advising providers of changes to the prescribing information for codeine. Codeine is now contraindicated for use in children for post-operative pain following tonsillectomy and/or adenoidectomy. An alternative analgesic should be prescribed for pain in children following these procedures. <p>ii. DUR Educational Alert (July, 2013): Valproate Products Contraindicated for Migraine Prevention in Pregnant Women</p> <ul style="list-style-type: none"> This alert summarized a recent FDA Drug Safety Communication reviewing changes to the prescribing information for valproate sodium and related products. The Neurodevelopmental Effects of Antiepileptic Drugs (NEAD) evaluated the IQ of children exposed to various anti-epileptic drugs in utero. Children exposed to valproate had lower cognitive test scores at age 6 compared to children exposed to other antiepileptic drugs. Valproic acid and divalproex sodium, are now contraindicated and should not be taken by pregnant women for the prevention of migraine headaches. <p>iii. DUR Educational Bulletin (August, 2013): Improving the Quality of Care: Therapeutic Monitoring of Anticonvulsants</p> <ul style="list-style-type: none"> This bulletin used a retrospective cohort study to assess the rate of drug serum concentration level monitoring among the Medi-Cal fee-for-service population for phenobarbital, carbamazepine, phenytoin, divalproex sodium and valproic acid for a one-year period. The overall annual monitoring rate was found to be 56.6%, which is similar to the annual monitoring rate noted for commercial and Medicaid HMO populations in 2011. <p>g. Retrospective DUR</p>

i. Review of Retrospective DUR Criteria: Opiate agonists and partial agonists

- Paid claims for narcotics with dates of service between 10/1/11 – 9/30/12 were reviewed and data were presented to the Board. Several ideas for further research in this area were endorsed by the Board including the following: 1) conducting an evaluation of opioid use in Medi-Cal FFS beneficiaries with a concomitant diagnosis of a mental health condition, providing treatment guidelines for managing pain in this population; 2) evaluating treatment guidelines for managing pain among children and adolescents (age 24 years and younger, with age stratification of 0-5, 6-11, 12-17, 18-24), including an evaluation of the trend over time in the prevalence of opioid use in the child and adolescent Medi-Cal FFS population; 3) summarizing the red flags for potential substance abuse and/or prescription drug diversion in the doctor's office and the pharmacy, including information on proper procedure and rules for dispensing controlled substances, and the legal and clinical responsibilities for all health care providers in cases of suspected prescription drug addiction and/or prescription drug diversion of controlled substances; and 4) A brief alert to providers promoting the California Department of Justice (DOJ) Controlled Substance Utilization Review and Evaluation System (CURES) Program.
- All proposed topics for further review were accepted by the Board, including the following: 1) reviewing the impact of restrictions on tramadol enacted by DHCS on dates of service on or after October 1, 2012, including a maximum quantity restriction of 240 tablets per dispensing and a maximum duration of therapy of 90 days; 2) assessing opioid use and mortality in the Medi-Cal FFS population, linking death index information with medical and pharmacy claims data (would exclude patients with ICD-9 diagnosis for cancer); 3) conducting an in-depth evaluation on the utilization of promethazine with codeine in the Medi-Cal FFS population to determine if it should be subject to additional prospective DUR alerts or quantity limits; 4) conducting an in-depth evaluation on the utilization of opioids among women in the Medi-Cal FFS population, as recent data show deaths from prescription painkiller overdoses among women have increased more than 400% since 1999, compared to 265% among men; and 5) conducting an in-depth evaluation on the utilization of narcotic withdrawal therapy agents, including possible concomitant use of opioids, in the Medi-Cal FFS population.
- The Board noted in the summary of paid claims there were a large number of opioids that contain acetaminophen and suggested an evaluation reviewing potential for acetaminophen toxicity in patients who take high levels of these opioids. Patrick Robinson mentioned that he believes First DataBank (FDB) has programmed for high dose and additive toxicity alerts for all acetaminophen products, alone and in combination. Xerox does not have the ability to review in FDB's Clinical Modules to validate the alerts, but all the generic sequence number (GSN) for these products could be turned on in test and report back. Dr. Albertson thought this would be of high value and motioned that all acetaminophen products GSNs are turned on in test for additive toxicity and high dose.

ACTION ITEM: Submit proposal to DHCS recommending conducting a test-run of prospective DUR alerts targeting high-dose and additive toxicity for acetaminophen-containing products.

ii. Review of Retrospective DUR Criteria: New drugs added to Contract Drug List in 2012

- During the Federal Fiscal Year 2012 (between 10/1/11 and 9/30/12), there were a total of twelve new prescription medications added to the Medi-Cal List of Contract Drugs (over-the-counter medications were excluded from this report). Utilization data (total number of paid claims and utilizing beneficiaries with at least one paid claim) were reviewed for each of these 12 drugs during the period between 5/1/11 and 2/28/13 (to allow at least 5 months of utilization data before and after the drug was added. The Board agreed this was an interesting topic and recommended reviewing utilization data for new drugs on an annual basis.

iii. Review of Retrospective DUR Criteria: Asthma

- During the past year, 119,051 Medi-Cal FFS beneficiaries had a qualifying ICD-9 code for asthma and 100,144 Medi-Cal FFS beneficiaries had a paid claim for a short-acting, inhaled

	<p>beta-2 agonist (albuterol, levalbuterol, metaproterenol, or pirbuterol) and 32,662 Medi-Cal FFS beneficiaries had both an ICD-9 code for asthma and a paid claim for a short-acting, inhaled beta-2 agonist. The Board recommended writing an educational bulletin to educate providers that asthma-related suffering, cost and death can be greatly reduced through effective treatment with long-term controller medications. The bulletin will include a summary of the Guidelines Implementation Panel (GIP) Report, which presents recommendations and strategies for overcoming barriers to the acceptance and utilization of the updated National Heart, Lung, and Blood Institute (NHLBI) National Asthma Education Prevention Program (NAEPP) clinical practice guidelines for asthma.</p> <p>h. Discussion/Recommendations for Future Educational Bulletins: The Board recommended prioritizing the educational bulletin on asthma and further investigating utilization of promethazine with codeine, tramadol, and total daily dosage of acetaminophen. Additional potential topics to review in the future include publicizing the CURES program and national initiatives focused on the balance between pain control and abuse.</p> <p>ACTION ITEM: Draft a DUR educational article on asthma quality of care in the Medi-Cal fee-for-service population.</p>
	<p>i. Epocrates Demonstration: Dr. Lynch reviewed both the Medi-Cal website method to look up drugs on the Medi-Cal List of Contract Drugs (CDL) and some of the features added (e.g., the ability to review an entire class of drugs and see coverage and potential restrictions in a user-friendly list) by using the Epocrates online tool, where the Medi-Cal List of Contract Drugs is available at: https://online.epocrates.com/. Pauline Chan reviewed the capabilities of the Epocrates mobile device application on an iPad.</p>
5) PUBLIC COMMENTS	None.
6) CONSENT AGENDA	<ul style="list-style-type: none"> The next Board meeting will be held on November 12, 2013, in the Auditorium at 1500 Capitol Avenue, Sacramento, CA 95814 (not DHCS Training Room B+C).
7) ADJOURNMENT	<ul style="list-style-type: none"> The meeting was adjourned at 12:36 p.m.

Action Items	Ownership
Look at how other state DUR Boards evaluate their data when they have both a managed and a FFS side and 2) reopen the discussion with Director Douglas and Dr. Wofford to see how other state DUR Boards handle the issue of cost.	Pauline
Edit minutes to reflect Dr. Stebbins' understanding of the time of denial of MIS/DSS access, and incorporate Dr. Wong's edits into the minutes.	Xerox
Revise Section 10, DUR: Introduction in the Medi-Cal DUR manual with updated annual report information and present to the Board at the next meeting.	Xerox
Revise Sections 20 and 35 of the DUR manual to reflect the inactive status of the excessive duration (MX) alert.	Xerox
A summary of the DUR Board recommendations for updating the DUR target drug list and formulary file alert table for antipsychotics will be submitted to DHCS for review.	DHCS/Xerox
Submit proposal to DHCS recommending conducting a test-run of prospective DUR alerts targeting high-dose and additive toxicity for acetaminophen-containing products.	DHCS/Xerox
Draft a DUR educational article on asthma quality of care in the Medi-Cal fee-for-service population.	DHCS/Xerox